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Factors that influence clinical trial participation by patients with cancer in Australia: a scoping review protocol

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ABSTRACT

Introduction Clinical trials are the backbone of research. It is well recognised that patient participation in clinical trials can be influenced by a myriad of factors such as access to a clinical trial, restrictive trial eligibility criteria and perceptions held by patients or physicians about clinical trials. Australia is a key stakeholder in the global clinical trials sphere. This scoping review protocol aims to identify and map the current literature describing factors that influence clinical trial participation of patients with cancer, in Australia.

Methods and analyses The Joanna Briggs Institute (JBI) methodology for scoping reviews will be used to conduct this review. Four electronic databases will be systematically searched for relevant published literature on this topic, as a collaborative process involving the lead investigator and a health science librarian. We will hand search of citations and reference lists of the included papers, and a grey literature search through Google scholar, Grey Literature Report, Web of Science Conference Proceedings. All published papers pertaining to patients diagnosed with solid organ or haematological malignancies will be included. Studies which did not involve patients from Australia will also be excluded. A customised data extraction tool will be pilot tested and refined, and subsequently two independent reviewers will perform data screening and extraction. Results will be collated and reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension for scoping reviews: PRISMA-Scoping Reviews. Quantitative data will be presented using descriptive statistics. Qualitative data will be synthesised using thematic analyses. This scoping review does not require ethical approval as the methodology focuses on analysing information from available published data.

Ethics and dissemination Results will be disseminated to relevant stakeholders including consumers, clinicians, professional organisations and policy-makers through peer-reviewed publications and national and international conferences.

Strengths and limitations of this study

- ► This will be the first scoping review to systematically search factors that influence clinical trial participation by oncology patients in Australia.
- ► This protocol outlines a transparent and rigorous study design which follows an established scoping review methodology.
- ► A thorough strategy was developed in consultation with an experienced medical librarian with validation from content experts.
- ► This review protocol will ensure a comprehensive range of grey literature is included.
- ► The scoping review is limited to the Australian health context and may be limited in its application to other health contexts.

INTRODUCTION

Clinical trials are important to the health ecosystem across all clinical subspecialties, including oncology. Participation in cancer clinical trials is fundamental for advancing oncology treatments, to improve survival and quality of life.[1] Offering participation in a clinical trial whenever possible is the best practice in cancer care.[2–5] However, despite well-documented benefits to quality of life and survival, trial enrolment rates have remained consistently low over decades.[1] Studies from the USA demonstrate that less than 5% of all patients with cancer are enrolled in a clinical trial.[6] Participation in the UK is slightly higher with almost 11% of adult patients with newly diagnosed cancer participating in trials.[7] Interestingly, research has shown that 55% of patients with cancer who were offered a clinical trial did in fact participate.[8] Furthermore, over 70% of patients with cancer in the USA were estimated to be either willing or very willing to participate in a clinical trial if offered.[9] There are discrepancies between overall enrolment rates and participation when patients are offered a clinical trial. These factors appear compounded by perceived willingness to participate, suggesting additional factors are influencing clinical trial participation in cancer care.

For this reason, we have commenced a body of work to better understand the current evidence. First, we have completed a

rapid review of the international evidence on the factors that influence clinical trial participation in patients with cancer, to better obtain a robust understanding of the state of play. This exercise identified that there have been factors identified in health contexts internationally, such sociodemographic factors (age, ethnicity, health literacy and financial situation), access factors (transportation, travel costs, access to insurance) to reach trial sites, clinical factors (such as restrictive trial eligibility criteria) and attitudinal factors on the part of both the potential participant and the investigator.[1 10–12] More than half of all patients with cancer (56%) did not participate in trials because there were no trials available that matched the patient's cancer type and stage at the centre where they received treatment.[13] In the event of a trial being available, only 20% of patients were eligible due to strict study criteria.[13] Taken together, these data suggest that more than three out of four patients do not participate due to factors related to availability or narrow eligibility criteria.[13] Furthermore, when a clinical trial is available and the patient would be eligible to participate, physician-related or patient-related factors can subsequently influence participation.[8] Earlier studies have highlighted physician decision or preference as the primary reason for non-participation in half of the patients for whom a trial was available and the patient was eligible.[14 15] Reasons which deterred physicians from recommending trial participation to their patients included limited time and funding resources, treatment preferences and nature of study regimen.[1] From the patient perspective, we know that informed consent is a key step in clinical trial participation. Autonomy in decision-making, loss of control, fear of side effects, concerns about costs and logistical barriers such as transportation arrangements have been described as reasons for patients to decline trials.[1] The impact of the health service model is largely under-reported. These findings suggest that there are many layers of complexity that influence trial participation outside of patient disinterest. Many evidence gaps remain, including those from different national health contexts, such as Australia.

Despite the fact that Australia is a major global contributor to clinical trials, there is a stark lack of high-level synthesis of the available Australian data relating to this topic. Australia is recognised internationally as a top-tier country for clinical trial activity per capita, with a track record of clinical excellence.[16 17] Pre-COVID-19, of the 9300 industry sponsored trials started in 2019 internationally, 1877 were in Australia.[17] Even with a modest population of 25 million people, Australia contributes a large share of industry-sponsored clinical activity at 5% of the global market, with approximately a quarter of all activity in the oncology setting.[17] During the ongoing COVID-19 crisis which has led to decreased clinical trial activity internationally, Australia managed to preserve and grow the clinical trial sector in oncology.[17] This showcases Australia's role as a key stakeholder in industry-sponsored clinical trial implementation.

Australia is the world's sixth largest country by land area[18] but due to smaller population, it is considered one of lowest population density in the world.[19] With key differences in demographics, geography and healthcare systems compared with other Organisation for Economic Co-operation and Development (OECD) countries, direct extrapolation of factors identified in the international literature influencing clinical trial participation may not be feasible to the Australian context. One-third of the population living outside of major cities and 3% residing in remote or very remote areas.[19] It is also one of the world's most culturally diverse countries, with almost one-third (30%) of the population born overseas and almost one-fifth (19%) speaking a language other than English at home.[20] Over 3% of the population are Aboriginal and/or Torres Strait Islander with over two-thirds of Indigenous people residing away from major urban centres. Some published work to date highlights under-representation in clinical trial participation for certain patient populations in Australia such as culturally and linguistically diverse people, Aboriginal and/or Torres Strait Islander Australians, and those residing in rural or remote areas.[21–24]

Australia also has a two-tiered healthcare system with public and private healthcare providers under the umbrella of universal healthcare. The majority of cancer care, including most clinical trials, is conducted in the public health sector.[25] How all these factors influence clinical trial participation in the Australian has not been explored in the literature and may give rise to a much more comprehensive understanding of oncology clinical trial participation internationally.

This knowledge gap has been confirmed by a preliminary search of the literature in the PROSPERO, Cochrane Database of Systematic Reviews, JBI Evidence Synthesis, Medline (PubMed) and CINAHL (EBSCO) on 10 June 2021. We identified that there are no current or underway scoping reviews or systematic reviews on the factors that influence oncology trial participation in Australia.

In response, we have developed a scoping review protocol that aims that will identify and report on the factors that influence clinical trial participation by patients with cancer in Australia. When referring to trial 'participation', the aim is to capture all aspects of participation including patient recruitment, engagement and retention. The research objective of this study is to identify, gather and map the existing research exploring the factors that influence clinical trial participation by patients with cancer in Australia. The findings will be shared with professional and public stakeholders to collaboratively identify and prioritise future directions of clinical research and inform policy.

METHODS

This scoping review will be conducted in accordance with Joanna Briggs Institute (JBI) methodology for scoping reviews.[26] Preliminary searches were conducted to

develop the search strategy. Final searches, screening and data extraction will be completed on 30 March 2022. The scoping review will be finalised 30 May 2022.

Inclusion criteria

Participants

Studies included will relate to patients with cancer. Those studies relating to patients with both haematological and non-haematological (solid organ) cancers will be included. There will be no age restrictions.

Concept

Studies considered will report on factors that influence clinical trial participation by patients with cancer in Australia. The definition of cancer clinical research is broad. For the purposes of this scoping review, the working definition of clinical trials will exclude other clinical research such as database registries, tumour banks, translation studies and supportive cares. As mentioned previously, the term participation is aimed to capture all aspects of patient participation which includes patient recruitment, engagement and retention.

Context

Any literature that involves patients participating in cancer clinical trials in Australia will be considered. This includes those that include Australia and other countries in their study. We will exclude any literature that does not include Australia.

Types of sources

A broad range of study designs will be included to produce a comprehensive map. This scoping review will consider both experimental and quasi-experimental study designs including randomised controlled trials, non-randomised controlled trials, before and after studies and interrupted time-series studies. Analytical observational studies including prospective and retrospective cohort studies, case-control studies and analytical cross-sectional studies will be considered for inclusion. Descriptive observational study designs including case series, individual case reports and descriptive cross-sectional studies will be included.

This review will also include qualitative studies, mixed methods study designs and grey literature comprising letters, editorials, conference reports, research reports, theses/dissertations that relate to our review. Textual and descriptive papers will also be included in this scoping review. Policy documents from government organisations, healthcare services, professional bodies and consumer advocacy groups will be included.

In addition, systematic reviews that meet the inclusion criteria will also be considered, depending on the research question. There will be no limitation in year or time frames and there will be no limits on language.

Search strategy

The search strategy will aim to locate both published and unpublished primary studies, reviews, and texts and opinion papers. In collaboration with a health science librarian, an initial limited search of Medline (Ovid) and CINAHL (EBSCOHost) was initially undertaken to identify articles on topic. The text words contained in the titles and abstracts of relevant articles, and the index terms used to describe the articles were used to develop a full search strategy for Medline via OVID (see online supplemental appendix 1). The search strategy, including all identified keywords and index terms, will be adapted for each included information source. The reference lists of included full-text articles will be screened for additional articles.

All studies will be in English. There will be no date limitations.

The databases to be searched include Medline (Ovid), CINAHL (EBSCOHost), EMBASE (Elsevier) and Scopus (Elsevier). We will also manually search all reference lists of included studies to identify additional studies of relevance. Sources of unpublished studies and grey literature to be searched include Google scholar, Grey Literature Report, Web of Science Conference Proceedings. A variation of key words mentioned in online supplemental appendix 1 will be used in Google Scholar filtered to only portable document format (PDF) files s and Australian websites. All pages on Google Scholar will be reviewed.

We will also conduct a targeted search of the grey literature in in local, state and national organisations' websites, clinical trial organisations and collaborative groups.

Source of evidence

Following the search, all identified citations will be exported into the reference manager EndNote V.X9 (Clarivate Analytics). EndNote V.X9 will subsequently be used to remove duplicates. An initial pilot test of screening 10 evidence sources between two independent reviewers will be conducted to ensure clarity and consistency in the application of the inclusion and exclusion criteria during the title and abstract screen. Following the pilot test, titles and abstracts will then be screened by two reviewers independently for assessment against the inclusion criteria for the review in the JBI System for the Unified Management, assessment and Review of Information (JBI SUMARI; Adelaide, Australia).[27 28] Potentially relevant sources will be retrieved in full. Following a similar process of pilot testing, two independent reviewers will assess the full text of selected citations in detail against the inclusion criteria. Reasons for exclusion of sources of evidence at full text that do not meet the inclusion criteria will be recorded for later reporting in scoping review. Any disagreements that arise between the reviewers at each stage of the selection process will be resolved through discussion, or with a third reviewer. The results of the search and the study inclusion process will be reported in full in the final scoping review and presented in a Preferred Reporting Items for Systematic Reviews and Meta-Analyses-Scoping Reviews flow diagram.[29]

Data extraction

Data will be extracted from identified evidence sources by two independent reviewers using a data extraction tool

based on the standardised tool from JBI SUMARI.[26 30] The data extracted will include specific details about the participants, concept, context, study methods and key findings relevant to review objective.

The draft charting table is provided (see online supplemental appendix 2). It serves as an extraction tool designed with authors to ensure all relevant results are extracted. Relevant data will include author, year of publication, country(ies) of origin, study design or type of paper, aims/purpose, population (age, type of cancer, stage, study subject population), sample size, study design, study method and healthcare setting (eg, hospital, community). Outcomes and outcome measures (if applicable) will be collected based on previous identified factors in systematic reviews.[8] To ensure we capture all information, free-text data collection will be available. Key findings, limitations and quality issues will also be collected.

The draft data extraction tool will be initially piloted for six evidence sources to assess reliability, consistency, usability and appropriateness. The number of evidence sources for piloting was selected following preliminary number papers found in initial limited search. As data extracting in scoping review is typically an iterative process, it is expected that the data extraction form will be further developed during initial extraction pilot. Regular meetings between the data extractors will occur during this stage to ensure the data extraction tool continues to be appropriate for evidence being extracted, and to assess if potential modifications are required to the tool. If modifications are required, these changes will be applied to all included studies. Modifications from draft data extraction form will be detailed in the scoping review report. Any disagreements that arise between the two reviewers will be resolved through discussion, or with a third reviewer. Authors of papers will be contacted to request missing or additional data, where required.

Data analysis and presentation

The extracted data will be collated and summarised. The quantitative data will be analysed descriptively. Aggregated results will be presented to align with the objective of this scoping review. Qualitative data will be extracted by two reviewers independently into tables and organised into matrices so that key themes can be identified.[31]

The overall findings will be discussed using a mixed methods approach.[32]

Patient and public involvement

The public were not involved in the development of this protocol. We sought advice from a carer and consumer representative to develop the constructs informing this protocol, and they will be involved as partners in planned research moving forward.

DISCUSSION

The aim of this scoping review is to identify and map factors that impact patient participation in clinical trials in Australia. It is intended that this scoping review protocol will enable a comprehensive understanding of all the mechanisms that influence oncology patient participation in Australia. This scoping review protocol is a part of a larger body of work that aims to build new knowledge that can be used improve design and delivery of oncology clinical trials so that greater equity and access ensues. It is our intention that by comprehensively investigating this issue in Australia, we can generate new knowledge that can give guidance for similar work in other health systems. It is also intended that by building on the work proposed in this scoping review protocol, there may be an opportunity to inform health policy that better supports the oncology clinical trial sector so that a larger community of patients and their families can benefit.

CONCLUSION

To our knowledge, this would be the first attempt at high-level synthesis of the Australian data on this topic. There remains a limited understanding of the factors influencing participation in the clinical trials. This scoping review protocol can potentially lead to improvements in future clinical trial design, policy infrastructure and practice.

ETHICS AND DISSEMINATION

Ethical approval is not required as this work will summarise studies that have already undergone review in keeping with journal policies. The results that come from the scoping review will be disseminated at relevant conferences. There will be a collaborative opportunity to inform health policy that better supports the oncology clinical trial sector so that a larger community of patients and their families can benefit.

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Contributors KHY: validation, investigation, data curation, writing-original draft, writing-review and editing. NR, ZL: conceptualisation, methodology, writing-original draft, writing-review and editing, investigation, visualisation, supervision. EA: conceptualisation, methodology, writing-review and editing, investigation, supervision. DW: conceptualisation, methodology, writing-review and editing, supervision.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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Supplementary Material I: Search strategy

MEDLINE (PubMed)

Date of search: July 27, 2021

Search	Query	Records retrieved
S1	"Clinical Trials as Topic"[Mesh] OR "Clinical Trial" [pt] OR "multicenter study"[pt] OR "randomized controlled trial"[pt] OR "Clinical Trials as Topic"[mesh:noexp] OR "controlled clinical trials as topic"[MeSH Terms:noexp] OR "randomized controlled trials as topic"[MeSH Terms:noexp] OR "early termination of clinical trials"[MeSH Terms:noexp] OR "multicenter studies as topic"[MeSH Terms:noexp] OR clinical trial*[tiab] OR randomized [tiab] OR randomly [tiab] OR trial [ti]	1,996,035
S2	"Neoplasms"[Mesh] OR "Medical Oncology"[Mesh] OR Neoplasm*[Tiab] OR Cancer*[Tiab] OR Tumor*[Tiab] OR tumour*[tiab] OR Oncolog*[tiab]	4,446,554
S3	"Patient Participation"[MeSH] OR "patient participation"[tiab] OR "patient engagement" [tiab] OR "patient involvement" [tiab] OR "Patient Selection"[MeSH] OR Enrol[ti] OR enrolment[ti] OR recruitment[ti] OR retention[ti] OR disparit*[tiab] OR barrier*[ti] OR inequalities[tiab] OR inequit*[tiab] OR attitude*[tiab] OR knowledge[ti] OR enabler*[tiab] OR "Health Knowledge, Attitudes, Practice"[MeSH] OR "Physician-Patient Relations"[MeSH]	663,170
S4	Australia*[tiab] OR “Australia”[MeSH]	213,085
S5	S1 and S2 and S3	12,317
S5	S1 and S2 and S3 and S4	337

Supplementary Material II: Data extraction instrument

Publication details	Study name/Title of article Author Date of publication

	Country/Region Publication type
Study details	Study aims Population (age, type of cancer, stage, study subject population) Sample size Study design Study method Health care settings
Results/Outcomes	Study outcome measures: No trial available yes / no / N/A Difficulty accessing health care due to transportation yes / no / N/A Patient ineligible due to study criteria yes/ no /N/A Physician led decision yes / no / N/A Patient led decision yes / no / N/A Other findings : (free text) Study outcomes : (free text)
Key findings	Key findings that relate to this review's question
Limitations/quality issues.	